

Food and Drug Administration Rockville MD 20857

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The Honorable Sam Farr House of Representatives Washington, D.C. 20515-0517

Dear Mr. Farr:

Thank you for your letter of May 20, 1999, concerning actions by the Food and Drug Administration (FDA or the Agency) in regard to labeling of foods treated with ionizing radiation.

The 1997 FDA Modernization Act (PL 105-115) states that "[n]o provision . . . shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients . . ." FDA published a final rule implementing this provision of the law in the <u>Federal Register</u> of August 17, 1998. A copy of this regulation, along with the pre-existing labeling requirements for food treated with ionizing radiation (21 CFR 179), are enclosed for your information.

In addition, the Statement of Managers accompanying the FDA Modernization Act directed FDA to publish for public comment further proposed changes to the Agency's current labeling regulations. The managers stated their intention that any required labeling be of a type and character such that it would not be perceived to be a warning or give rise to inappropriate consumer anxiety. On February 17, 1999, FDA published an Advance Notice of Proposed Rulemaking (ANPR) in the Federal Register soliciting public comment on whether additional revisions to the current irradiation labeling requirements are needed and, if so, what form such revisions might take. The deadline for comments in response to the ANPR has been extended to July 19, 1999.

We have forwarded your correspondence to the Docket for inclusion in the record. FDA's final approach to labeling of irradiated foods will take into account all of the data and information received.

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In regard to irradiation labeling for meat and poultry, you may also wish to contact the United States Department of Agriculture (USDA) for information. (USDA has primary regulatory authority over meat and poultry products, including the labeling of such products.)

We have also enclosed some general background on the issue of irradiation. We trust this responds to your concerns. If we may be of further assistance, please contact us again.

Sincerely,

Melinda K. Plaisier

Interim Associate Commissioner for Legislative Affairs

Enclosures

cc: Dockets Management Branch (98N-1038)

SAM FARR
-127* DISTRICT, CALIFORNIA

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Congress of the United States House of Representatives

Washington, DC 20515-0517

May 20, 1999

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Dr. Jane E. Henney Commissioner Food and Drug Administration Department Of Health and Human Services 5600 Fishers Lane Rockville, Maryland 20807

Dear Dr. Henney:

I am writing to support a Petition for Stay in Administration Action in the above referenced manner, filed by People for Pure Foods, with the Dockets Management Brand of The Food and Drug Administration on May 4, 1999. People for Pure Foods, a national Public Interest group, filed this Petition, in the broad public interest, to request that the Food and Drug Administration extend the comment period for Docket 98N-1038 for one hundred and twenty (120) days, until September 15, 1999.

People for Pure Foods and numerous other Public Interest Groups request this extension to provide additional time to create greater awareness among consumers of the fifteen (15) queries posed by the Food and Drug Administration in the Federal Register, Vol. 64, No. 31, pp. 7834 - 7837, February 17, 1999. In addition, People for Pure Foods intends to bring this controversial proposal to the attention of Legislators attending the National Foundation of Women Legislators Annual Meeting in Pasadena, California in July, so that these states' Legislators may take the opportunity to submit their comments.

The portents of either changing or deleting the current regulatory requirement for the labeling of foods exposed to radiation, 21 C.F.R. 179.26, are of great concern to consumers, who want more information, not less, when making their food purchase choices. Therefore, I recommend that you give your favorable attention to granting the 120 day extension in the comment period for Docket No. 98N-1038. Thank you for your timely attention to this important matter.

Sincerely,

SAM FARR

Member of Congress

SF/dc1

No. 99-3753